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10/790,449	02/19/2004	Wei-Cheng Wang	P-3641.274	9920

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EXAMINER	
FLORY, CHRISTOPHER A	
ART UNIT	**PAPER NUMBER**
3762	

DATE MAILED: 06/13/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/790,449	WANG, WEI-CHENG	
	Examiner	Art Unit	
	Christopher A. Flory	3762	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *19 February 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-9* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-9* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *19 February 2006* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Specification

1. The abstract of the disclosure is objected to because there is a typographical error. Line 1 reads, "A method for moderation lower back pain includes," which should be corrected to read –A method for moderation **of** lower back pain includes—or –A method for **moderating** lower back pain includes--. Correction is required. See MPEP § 608.01(b).

2. The disclosure is objected to because of the following informalities: a typographical error on page 2, line 12 reading "are *both* all contained" should be changed to read –are all contained--.

Appropriate correction is required.

3. The disclosure is objected to because of the following informalities: there are instances of using multiple component names to describe the same part and reference number in the drawings. On page 3, lines 17-18, reference is made to both "fixing element "(10)" and "pad (10)." On page 3, lines 15 and 20, reference is made to both "heat element (13)" and "resistance (13)." While it can be understood that "resistance" is a synonymous descriptor to "heat element," and "pad" a type of "fixing element," in both cases the specification should be changed to use only one descriptor for each part to remove any confusion that might arise.

Appropriate correction is required.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 2 and 4 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 2 recites, "stimulation comprises at least a set of non-invasive electrical stimulation." Claim 4 recites, "stimulation comprises at least a pair of electrical stimulation." In both instances it is unclear whether Applicant means for the invention to comprise a set or pair of stimulation electrodes, or whether applicant intends to claim a method comprising a step of applying two or a set (two or more) electrical stimuli that differ in duration, frequency, or magnitude; or two or more similar stimuli that simply differ in time of onset (i.e. a pulsed series of electrical stimuli).

In the case that Applicant is claiming a device with two or a set of electrodes, the claims should be corrected to read –stimulating comprises at least a set of non-invasive electrical stimulation electrodes—for claim 2, and –stimulation comprising at least a pair of electrical stimulation electrodes—for claim 4. In the case that applicant is claiming a method with a step of applying two or a set of stimuli, the claims should be corrected to read –stimulating comprises at least a set of non-invasive electrical [stimuli/stimulation pulses]—for claim 2, and –stimulating comprises at least a pair of electrical [stimuli/stimulation pulses]—for claim 4. Appropriate correction is required.

Claim Rejections - 35 USC § 102

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

7. Claims 1-7 and 9 are rejected under 35 U.S.C. 102(b) as being anticipated by Stevenson et al. (US Patent 881,087).

Regarding claims 1-6, Stevenson et al. discloses a method of generating a stimulation signal to non-invasively stimulating the stimulation points surrounding K1 and FHA acupuncture points (Fig. 2; page 1, line 94 through page 2, line 2) with at least a set of non-invasive electrical stimulation (Fig. 2, galvanic elements D and D').

Further regarding claims 3, 5 and 6, the step of mounting a non-invasive stimulation device onto the stimulation points is satisfied when the user of the Stevenson device places a foot into the shoe. The combination of the weight of the user's body against the galvanic elements, as well as the tight lacing of the shoe, provide a sufficiently permanent or reliable electrical connection to the stimulating elements to be considered mounted. Therefore, this claim limitation does not distinguish over the prior art.

Regarding the clause "of/for moderating lower and upper back pain in a patient," it has been held that a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. In this case, the structure of the Stevenson et al. device is capable of delivering electrical stimulation to the sole of the foot in the same manner as the claimed invention, and would therefore logically and expectably be capable of the intended use of relieving back pain. Therefore, the claimed invention does not distinguish over the Stevenson et al. reference.

It is noted that, although Stevenson et al. does not explicitly state placement over the K1 and FHA acupuncture points, it is clear from Fig. 2 of Stevenson and Fig. 1a of the instant application that the Stevenson device delivers electrical stimulation to the claimed foot region, and therefore the claimed invention does not distinguish over the prior art.

Regarding claim 7, Stevenson et al. discloses a multiple electrode carrying insole (Fig. 2, insole C; TITLE; page 1, lines 9-22) housed in a shoe-like device (Fig. 1, shoe A; page 1, lines 33-40) carrying the at least two electrodes (Fig. 2, galvanic elements D, D') and a circuit for generating the stimulation signal (metal strip F); providing a securing means for mounting the at least two electrodes on the said insole (members E, E' and strip F, shown riveted to insole C; page 1, lines 73-92).

Regarding claim 9, Stevenson et al. discloses a constant stimulation effect while the shoe is being worn (page 1, line 95 through page 2, line 34).

8. Claims 1-9 are rejected under 35 U.S.C. 102(e) as being anticipated by Unsworth et al. (US Patent 6,615,080).

Regarding claims 1-6, Unsworth et al. discloses a method of generating a stimulation signal to non-invasively stimulating the stimulation points surrounding K1 and FHA acupuncture points (Figs. 7 and 10; ABSTRACT; column 3, lines 50-55) with at least a set of non-invasive electrical stimulation (Fig. 7, electrodes 6a and 6b); said method comprising mounting a non-invasive stimulation device onto the stimulation points (electrodes are disclosed as being self-adhesive in column 5, line 65 through column 6, line 3).

Regarding the clause "of/for moderating lower and upper back pain in a patient," it has been held that a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. In this case, the structure of the Unsworth et al. device is capable of delivering electrical stimulation to the sole of the foot in the same manner as the claimed invention, and would therefore logically and expectably be capable of the intended use of relieving back pain. Unsworth et al. discloses the device as being effective in increasing blood flow in the stimulated region (column 6, lines 4-11), which Applicant discloses in paragraph [22] as

a component of end result of back pain relief. Therefore, the claimed invention does not distinguish over the Stevenson et al. reference.

It is noted that, although Unsworth et al. does not explicitly state placement over the K1 and FHA acupuncture points, it is clear from Fig. 10 of Unsworth et al. and Fig. 1a of the instant application that the Unsworth et al. device delivers electrical stimulation to the claimed foot regions of the ball and heel (column 3, lines 50-55), and therefore the claimed invention does not distinguish over the prior art.

Regarding claim 7, Unsworth et al. shows a multiple electrode carrying insole (Fig. 7, insert 17) housed in a shoe-like device (Fig. 7, footwear 15) carrying the at least two electrodes (electrodes 6a and 6b) and a circuit for generating the stimulation signal (NMES device 10; column 5, line 43 through column 6, line 11); providing a securing means for mounting the at least two electrodes on the said insole (column 10, lines 9-26).

Regarding claim 8, Unsworth et al. discloses a delivering step comprising delivering an intermittent stimulation signal (column 5, lines 52-63). The intermittent stimulation signal is taken to be the cycle of 12 seconds on and 48 seconds off.

Regarding claim 9, Unsworth et al. discloses a delivering step comprising a continuous stimulation signal (column 5, lines 52-63). The continuous signal is considered to be the biphasic square wave pulses that are delivered for a continuous 12 seconds. Likewise, it is understood from the user interface as disclosed in Unsworth et al., that the device continues to deliver biphasic pulses in a 12 seconds on, 48 seconds off manner until the user adjusts the intensity dial to zero (i.e. "off"). Therefore, this can

be considered a stimulation signal (wherein the signal is considered to be the overall stimulation pattern) that is delivered continuously from the time the device is put on until the user makes the decision to take the device off or turn the stimulus intensity to zero, or effectively turn the device off. Given either or both interpretations, this claim limitation of the instant application does not distinguish over the prior art.

Claim Rejections - 35 USC § 103

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

10. Claim 1 is rejected under 35 U.S.C. 103(a) as being unpatentable over Examiner's Official Notice.

Examiner takes official notice that it is possible to non-invasively and concurrently stimulate the group of stimulation points surrounding K1 and FHA acupuncture points by manually applying pressure and rubbing each of these areas on the soles of the feet with a thumb or finger, or a combination thereof, in order to moderate lower and upper back pain.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christopher A. Flory whose telephone number is (571) 272-6820. The examiner can normally be reached on M - F 8:30 a.m. to 5:00 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on (571) 272-4955. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Christopher A. Flory

7 June 2006

George Manuel
Primary Examiner